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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/699,716	08/27/1996	DAVID G. HEATH	003/029/SAP	3555

7590

01/31/2002

US ARMY MEDICAL RESEARCH &
MATERIAL COMMAND
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FORT DETRICK FREDERICK, MD 217025012

EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 01/31/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/1699, 711

Applicant(s)

Heath

Examiner

DUFFY

Group Art Unit

1645

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on CPA 4-9-01 + Amends 4-9-01 + 9-12-01
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-3, 5-17, 30-31 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-3, 5-17, 30-31 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

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DETAILED ACTION

1. The request filed on 4-9-01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/699,716 is acceptable and a CPA has been established. An action on the CPA follows.
2. The amendment filed 4-9-01 and 9-12-01 has been entered into the record. Claims 1-3, 5-17, 30 and 31 are pending and under examination.
3. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

4. The rejection of claim 31 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of Applicants claim amendments.

Rejections Maintained

5. The rejection of claim 11 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn over claim 15 only, the rejection over claim 11 is maintained for reasons made of record.

The examiner acknowledges that Applicants will deposit the plasmid and will provide the deposit information when it becomes available. Until such time as the deposit requirements have been met, the rejection is maintained.

6. The rejection of claim 31 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons made of record in Paper No. 8, mailed 11-10-97.

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The rejection is maintained. No *Yersinia* DNA V antigen homologues are described in the specification or by the art. Applicants amendments are insufficient to remove this rejection as it applies to claim 31.

7. The rejection of claims 1-3 and 5-17, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/18231 (Titball et al.-31) and further in view of: WO 95/24475 (Titball et al.-'75); or Leary et al. Infection and Immunity 63(8): 2854-58 8/95, publicly available as of 7/25/97) is maintained for reasons made of record in Paper No. 17, mailed 2-1-00.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue Titball -'75 is not proper prior art since it was publicly available on 14 September 1995, less than one year before the filing date of the claimed invention. This is not persuasive, Applicants are directed to 35 USC 103(a) that states:

"(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

It is noted that this rejection is a 103 based on a 102(a) reference of Titball-'75. The rejection is proper because Titball is by another. Titball-'75 is prior art to this application and Applicants admit such. Applicants argue that Titball-31 does teach the production of fusion proteins. This is simply not so. Titball-31 at pages 5-7 teach "The inventors have determined the sequence of a still further preferred recombinant DNA which when included within suitable vectors within, or integrated directly into the chromosomal DNA of , gut dwelling microorganisms results in still stronger expression of protective F1, **F1 fusion** [emphasis added] or F1 truncate proteins. all in addition to the caf1 gene encoding the F1 subunit or a truncate or **fusion product** [emphasis added] thereof." At page 6: "SEQ ID No 6: is that of pFSIG3a: including caf1 sequence encoding mature **F1 expressed as a fusion** [emphasis added] with the E. coli LTB signal sequence encoded by the vector

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and having a 5' tail including vector bases.". Clearly, Titball-'31 teaches fusion proteins and produces a protein characterized and taught as a fusion protein. The teachings of Titball-31 are unambiguous, fusion proteins with F1 are taught, contemplated and in Titball's own words, the mature F1 was expressed as a fusion. Clear guidance is provided for producing an F1 fusion protein. Moreover, plasmid pFGAL2a encodes a fusion protein of the initial 17 amino acids of β -galactosidase, expressed from the lac promotor (see Oyston et al; reference VR in the IDS filed August 27, 1996). Applicants again argue that the references alone or in combination do not teach or suggest the claimed invention. This is not persuasive for reasons already made of record in Paper No. 17, mailed 2-1-00 and reiterated herein. "Applicants argue that the references do not suggest the claimed DNA. This is not persuasive. *In re Fine*, 837 F.2d 1071, 1075, 5U.S.P.Q.2d 1959 (Fed. Cir. 1988) states that under section 103 a *prima facie* case of obviousness can be established by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art can lead the individual to combine the references. In the instant case the examiner has provided ample motivation to make a fusion protein

"..it would have been obvious to one of ordinary skill in the art to link the gene encoding the F1 protein as set forth by Titball et al. 31 to the gene encoding the V antigen as set forth by Leary et al since a DNA construct encoding the fusion protein would have been expected to provide a vaccine with higher efficacy than a DNA construct which only encodes for the V antigen (or F1 antigen). Furthermore, it would have been obvious for one of ordinary skill in the art to link the gene encoding the F1 protein to the gene encoding the V protein since the time and cost to make a F1 antigen fused to the V antigen would have been expected to be less than making the antigens independently. "... it would have been obvious to one of ordinary skill in the art to link the gene encoding the F1 protein as set forth by Titball et al. 31 to the gene encoding the V antigen as set forth by Titball et al -75 since a DNA construct encoding the fusion protein would have been expected to provide a vaccine with higher efficacy than a DNA construct which only encodes for the V antigen (or F1 antigen). Furthermore, it would have been obvious for one of ordinary skill in the art to link the gene encoding the F1 protein to the V protein

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since the time and cost to make a F1 antigen fused to the V antigen would have been expected to be less than making the antigens independently."

Applicants' arguments are not persuasive and the rejection is maintained for reasons made of record.

New Objections/Rejections

Claim Objections

8. Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. the claim recites a fragment that is less than the full length nucleotide sequence encoding the protein of claim 2. As such, claim 6 is considered to broaden the scope of the claim from which it depends, claim 2.

9. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by GenEMBL Accession Number M26405, Published 26 April 1993.

The claim is drawn to at least 30 consecutive nucleotides of the fusion protein of claim 2. GenEMBL Accession Number M26405 teaches the nucleotide sequence of the V antigen of *Y. pestis*. As such, the claim is clearly anticipated.

Status of Claims

10. All claims stand rejected.

11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone

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number is (703) 305-7555. The examiner can normally be reached on Monday-Thursday and Saturday from 10:30 AM to 7:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
January 28, 2002

Patricia A. Duffy
Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600

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BASE COUNT
688 a 453 c 461 g 528 t
ORIGIN

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	Matches 980;	Conservative	0;	Mismatches 1;	Indels 0;	Gaps 0;			
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DB	481	ATGATTAGAGCCTCAGCAACAAACCCACAACTTTTATTAGAGATCTGAAAAATTAGG							
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QY	706	GATPAAAAATATAGATATTTCATTTAAATATATATCCACAAAAAGATTGCGAGCTTTTGGC							
DB	601	GATPAAAAATATAGATATTTCATTTAAATATATATCCACAAAAAGATTGCGAGCTTTTGGC							
QY	766	AATAGAGAAATATACGATGATATCGAATTGCTCAAGAAAAATCCATAGCTTATTTTCTCTCC							

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[illegible]